This record is a partial extract of the original cable. The full text of the original cable is not available.

UNCLAS SECTION 01 OF 02 TAIPEI 004936

SIPDIS

STATE FOR EAP/RSP/TC AND EB/TPP/BTA, STATE PASS AIT/W AND USTR, USTR FOR WINELAND, WINTERS, AND STRATFORD, USDOC FOR 4431/ITA/MAC/AP/OPB/TAIWAN/MBMORGAN AND JDUTTON

E.O. 12958: N/A
TAGS: ETRD ECON TW ESTH
SUBJECT: MEDICAL DEVICE REGISTRATION DEADLINE LEAVES 25% UNDONE

REF: A. TAIPEI 4396
¶B. TAIPEI 2731
¶C. TAIPEI 2626

¶1. Summary: The December 20 deadline for medical device registration passed with only about 75% of medical devices currently in use in Taiwan receiving licenses. Those that have not yet received licenses are primarily in-vitro diagnostic devices. In most cases, the Department of Health (DOH) has not rejected the application, but is requesting additional documentation prior to issuing licenses. Manufacturers have four months to comply. Hospitals can continue to use products in stock, but companies are prohibited from importing or selling any device without a license. DOH has promised to issue emergency import licenses to non-substitutable products if the need arises. End Summary.

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Mixed Message at Deadline
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¶2. December 20 was the DOH imposed deadline for all medical devices to be registered and licensed before being legally imported or sold in Taiwan. This requirement, first announced in 2004, had already been postponed once when it became clear that DOH lacked the manpower and technical expertise to process the resulting thousands of applications. DOH proudly announced December 9 that it had processed 100% of applications in most categories and was confident that only a few applications for in-vitro diagnostic (IVD) devices would remain unprocessed by the deadline.

¶3. This promising news was tempered by reports from American medical device firms that large numbers of products in some categories have been processed but have not yet received licenses. As predicted (reftel A), these are mostly IVD devices. American companies estimate that more than 1000 devices are still awaiting DOH approval. DOH has requested additional documentation for many of these pending applications. In some cases, companies may have inadvertently misclassified devices, leading to additional delays. In other cases, reviewers have determined that kits containing several products designed to be used together need several licenses, again causing delays as companies struggle to provide additional information or submit new registration applications.

¶4. DOH says the delays are the fault of the companies that did not submit complete applications or request needed clarifications before submitting product applications. Companies counter that the registration requirements are sometimes unclear. DOH's use of poorly trained contractors to process applications has resulted in an inconsistent application of rules and sometimes strange requests for additional documentation. Many companies tell AIT, in addition to preparing their own registration applications; they have had to informally train DOH contractors as well.

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DOH to Approve Emergency Imports if Needed
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¶5. DOH Bureau of Pharmaceutical Affairs Deputy Director General Liu Li-ling told AIT December 20 that over 75% of the registration applications received by June 20 had already been approved. The remaining 25% have four months to submit additional documents or requested information. These will be approved as soon as the additional information is received, she said. If companies are not able to provide the requested information within four months, the application will have to be resubmitted.

¶6. DDG Liu added that hospitals could continue to use products that were already in stock, even if licenses had not yet been approved. However, companies are prohibited from importing or selling unlicensed products. This has reportedly led to hospital stockpiling of some products that have a long shelf-life. For those unlicensed products that do not have acceptable substitutes, hospitals can apply to DOH for an emergency temporary import license. DOH will

approve such emergency import applications almost immediately, said Liu.

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Comment: A Band-aid for Medical Devices
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¶7. In spite of complaints, DOH has done yeoman's work to process as many applications as they have over the past six months. They have approved over 8000 applications since the original June deadline. But the problem now faced by those medical device manufacturers still waiting for licenses should not surprise anyone. The medical device registration process has been marked by inconsistent decision-making, poor communication, and unmet expectations. That products already commonly used in Taiwan should face potential exclusion from Taiwan's market because of DOH's bureaucratic inefficiencies is a sad but telling commentary on the future of Taiwan's health care system. DOH's paternalistic and non-communicative culture make it difficult to implement new programs or promote meaningful reforms.

¶8. We expect DOH will use the emergency licensing process to avoid any serious wide-scale shortages of needed medical devices. That would be consistent with DOH's previous practice of cobbling together ad hoc solutions at the last minute -- DOH is adept at putting band-aids on more serious wounds.
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